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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,665	08/07/2003	Hiraku Murayama	029650-144	8895
21839	7590	06/08/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			HOEKSTRA, JEFFREY GERBEN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/635,665	Applicant(s) MURAYAMA ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 12-23 is/are rejected.
- 7) ☒ Claim(s) 12-15 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 03/20/2006, amended claim 1 is acknowledged, new claims 12-23 are acknowledged, and the amendments to the specification are acknowledged. The current rejections of the claims 1-3 are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claims 12-15, and 18 are objected to because of the following informalities:

3. Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

4. The term "about" in claims 13-15 is a relative term that appears to render the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The length of the first wire is unclear.

5. The term "nearly" in claim 18 is a relative term that appears to render the claims indefinite. The term "nearly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

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art would not be reasonably apprised of the scope of the invention. The orientation of the first and second wire connection end faces is unclear.

6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner notes a single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 22 positively recites a functional use of the claimed apparatus. The examiner notes the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of

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invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. at 1551. See MPEP 2173.05(p).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchino et al (US 6,001,068). Uchino discloses a guidewire 1 comprising a distally disposed reshapeable (as in the case of plastic or elastic deformation) metal first wire A and proximally disposed pseudo-elastic alloy second wire B (column 4 line 1) joined by spot or butt-resistance welding (column 7 lines 19-67 and column 8 lines 16-22) as best seen in Figures 1-3 wherein the connection end faces of wires A and B are nearly perpendicular to the axial direction of both wires A and B (column 7 lines 5-19) and wherein a the welded portion is located proximal the proximal end of a spiral coil covering at least a distal end portion of wire A as best seen in Figure 1, 9, 12, 14, and 17.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 2, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Jansen (US 5,365,943). Uchino et al discloses the claimed guidewire except for the third wire member proximally disposed to the second and the third member having a larger elastic modulus than the second. Jansen teaches having three wire members 44,46,48 comprising a guidewire wherein the most proximal member has the largest elastic modulus, stainless steel for example (column 6 lines 42-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with Jansen for the purpose of decreasing the flexibility from the distal to proximal regions of the guidewire by using different materials.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Abrams et al (US 5,341,818). Uchino et al discloses the claimed guidewire except for the taper of the guidewire extending from a region proximal the welded region of the proximal wire to a region distal the welded region of the distal wire. Abrams

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shows in Figure 1 a taper extending from a proximal region across a joint to the distal region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with Abrams for the purpose of configuring the guidewire to navigate tortuous vasculature.

16. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. Uchino et al discloses the claimed invention but does not disclose expressly the first wire ranging in length from 10 to 1,000 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the first wire of the guidewire as taught by Uchino et al with the claimed length range, because Applicant has not disclosed that disclosed length provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the distal most wire as taught by Uchino et al, because it configures the distal region of a guidewire for navigating tortuous vasculature and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino et al. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

17. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Palermo et al (US 5,769,796). Uchino et al discloses the claimed guidewire except for the welded portion between first and second wires located distal the proximal end of the spiral coil. Palermo et al teaches configuring the guidewire such that the welded portion is located distal the proximal end of a spiral coil as best seen in Figure

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5A. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with Palermo et al for the purpose of configuring the mechanical properties of the distal region of a guidewire for traversing tortuous vasculature.

Response to Arguments

18. Applicant's arguments with respect to structurally broad claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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